UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,172	09/08/2003	Asher Holzer	3049/1	1345

7590 07/21/2006

Martin D. Moynihan
c/o Anthony Castorina
2001 Jefferson Davis Hwy.
Ste. 207
Arlington, VA 22202

EXAMINER	
HELLER, TAMMIE K	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,172	HOLZER, ASHER	
	Examiner	Art Unit	
	Tammie Heller	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-13,18-23 and 28-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-13,18-23 and 28-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Species 4 in the reply filed on May 1, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Device claims directed towards attachment of the device to the human body are not statutory subject matter. However, claims to a device adapted to be attached to the human body is eligible statutory subject matter. The Examiner suggest revision of the claim to a "housing adapted to be attached to said heart tissue" to overcome this rejection.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims (1 and 37), (5, 6, 7), (11, 12, 13), 35, (20 and 21), 34, 28, and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 79, 80, 82, 84, 87, 89, and 90, respectively, of copending Application No. 11/102,624. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claims heart implant devices including a conductive coil and a ferromagnetic element.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5-7, 9, 10, 13, 18, 20, 32, 33, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hara et al. (U.S. Patent No. 6,183,125), herein Hara. Regarding claims 1 and 37, Hara discloses and electronic watch that is capable of being implanted into the body and includes a housing encompassing a space 10 and including a conductive coil 23 (see Figure 1). Further, Hara discloses a ferromagnetic element 24 disposed in space 10 which moves relative to the coil and produces electrical energy (see Figure 1 and col. 8, ln. 15-39).

7. Regarding claim 2, the Examiner takes the position that the size and shape of the electronic watch housing disclosed by Hara is inherently capable of being securely juxtaposed with the heart tissue.

8. Regarding claim 3, the Examiner takes the position that the size and shape of the electronic watch housing disclosed by Hara is inherently capable of being attached directly to the heart tissue.

9. Regarding claim 5, as is commonly known in the art, an electronic watch is designed to be disposed around the wrist of a user. Therefore, the electronic watch of

Hara is inherently of a ring-type design and therefore is capable of being disposed generally around a circumference of the heart.

10. Regarding claim 6, as discussed previously regarding claim 5, the electronic watch of Hara is inherently of a ring-type design, and therefore is capable of enveloping the heart by at least 180 degrees.

11. Regarding claim 7, as is commonly known in the art, an electronic watch is designed to be disposed around the wrist of a user. Therefore, the electronic watch of Hara is inherently of a ring-type design.

12. Regarding claims 9 and 10, the Examiner takes the position that the size and shape of the electronic watch housing disclosed by Hara is inherently capable of being securely associated with the epicardium or the pericardium.

13. Regarding claim 13, Hara discloses that the electronic watch is designed to produce electrical energy in response to bodily movement (see col. 8, ln. 17-27). The Examiner takes the position that the device of Hara is inherently capable of being attached to the heart tissue near a first end of the housing, and therefore producing electrical energy in response to movement of the heart tissue.

14. Regarding claim 18, it can be seen from Figure 1 that the conductive coil 23 is disposed externally to the housing defined by dynamo rotor 21.

15. Regarding claim 20, Hara discloses that the ferromagnetic element 24 is a shaft (see Figure 1).

16. Regarding claim 32, the Examiner takes the position that the size and shape of the electronic watch housing disclosed by Hara is inherently capable of being anchored between a myocardium and epicardium of the heart.

17. Regarding claim 33, the Examiner takes the position that the size and shape of the electronic watch housing disclosed by Hara is inherently capable of being anchored within a pericardium of the heart.

18. Claims 1-3, 9, 10, 13, 19, 20, 22, 23, and 28-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehr (U.S. Patent No. 3,906,960). Regarding claims 1 and 37, Lehr discloses an implantable medical energy converter which includes a housing 1 including a conductive coil 9 (see Figure 1). Further, Lehr discloses ferromagnetic elements 4-8 which are disposed within the space defined by housing 1 (see Figure 1 and col. 1, ln. 40-42). The ferromagnetic elements 4-8 of Lehr move relative to conductive coil 9 to produce electrical energy (see col. 1, ln. 60-63 and col. 2, ln. 1-7).

19. Regarding claim 2, Lehr discloses that the implant device may be securely juxtaposed with the heart tissue (see col. 2, ln. 34-35).

20. Regarding claim 3, Lehr discloses that the implant device may be attached directly to the heart tissue (see col. 2, ln. 34-35).

21. Regarding claim 9, the Examiner takes the position that the implant device of Lehr is inherently capable of being associated with an epicardium.

22. Regarding claim 10, the Examiner takes the position that the implant device of Lehr is inherently capable of being associated with a pericardium.

23. Regarding claim 13, Lehr discloses that the implant device is designed to produce electrical energy in response to movement of the heart tissue (see col. 1, ln. 60-63 and col. 2, ln. 1-7). The Examiner takes the position that the device of Lehr is inherently capable of being attached to the heart tissue near a first end of the housing.

24. Regarding claim 19, it can be seen in Figure 1 that the conductive coil 9 of Lehr is disposed within the housing 1.

25. Regarding claim 20, it can be seen in Figure 1 that the ferromagnetic element may be a shaft, like member 5.

26. Regarding claim 22, Lehr discloses that the housing includes a biocompatible external layer for contacting the heart tissue (see col. 1, ln. 46-47).

27. Regarding claim 23, Lehr discloses that the housing includes a biocompatible external layer which physically and electrically isolates the heart tissue from the coil (see col. 1, ln. 46-47).

28. Regarding claim 28, Lehr discloses the use of a pacemaking element for stimulating contractions of the heart tissue (see col. 2, ln. 18-24).

29. Regarding claim 29, the Examiner takes the position that the implant device of Lehr is inherently capable of being anchored between a myocardium and epicardium of the heart.

30. Regarding claim 30, the Examiner takes the position that the implant device of Lehr is inherently capable of being anchored within a pericardium encompassing the heart.

31. Regarding claim 31, Lehr discloses that the implant device may be anchored within a blood vessel, which would inherently include the coronary sinus (see col. 2, ln. 34-35).

32. Regarding claim 32, the Examiner takes the position that the implant device of Lehr is inherently capable of being anchored between a myocardium and epicardium of the heart.

33. Regarding claim 33, the Examiner takes the position that the implant device of Lehr is inherently capable of being anchored within a pericardium encompassing the heart.

34. Regarding claim 34, Lehr discloses that the implant device may be anchored within a blood vessel, which would inherently include the coronary sinus (see col. 2, ln. 34-35).

35. Regarding claim 35, Lehr discloses a spring mechanism for returning the ferromagnetic element from a wall of the housing (see col. 1, ln. 47-48).

36. Regarding claim 36, Lehr discloses providing a heart implant device associated with the heart of a living body which includes a housing 1 including a conductive coil 9 and ferromagnetic elements 4-8 disposed within the space defined by housing 1 (see Figure 1 and col. 1, ln. 40-42) which move relative to the conductive coil 9 to produce electrical energy (see col. 1, ln. 60-63 and col. 2, ln. 1-7).

37. Claims 1-3, 19, 21-23, 28, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Fink (U.S. Patent No. 4,661,107). Regarding claims 1 and 37, Fink discloses a pacemaker battery charging system that includes a housing 13 encompassing a space 19 including a conductive coil 17 (see Figures 3 and 4). Further, Fink discloses ferromagnetic element 12 which moves in space 19 relative to coil 17 to produce electrical energy (see Figure 3 and col. 2, ln. 64-68 and col. 3, ln. 1-3).

38. Regarding claim 2, Fink discloses a heart valve apparatus, which is inherently capable of being juxtaposed with the heart tissue.

39. Regarding claim 3 Fink discloses a heart valve apparatus, which is inherently capable of being attached directly to heart.

40. Regarding claim 19, it can be seen from Figure 4 that the conductive coil 17 of Fink is disposed within the housing 13.

41. Regarding claim 21, it can be seen from Figure 3 that the ferromagnetic element 12 is in the form of a ball.

42. Regarding claim 22, Fink discloses that the housing includes a biocompatible external layer for contacting heart tissue (see col. 5, ln. 9-10).

43. Regarding claim 23, Fink discloses that the housing includes a biocompatible layer which is capable of physically and electrically isolating the heart tissue from the coil (see col. 5, ln. 9-10).

44. Regarding claim 28, the device of Fink includes a pacemaking element 43 for stimulation contractions of muscle tissue in the heart (see Figure 6).

45. Regarding claim 36, Fink discloses providing a heart implant device associated with the heart of a living body which includes a housing 13 including a conductive coil 17 and ferromagnetic element 12 disposed within the space defined by housing 13 which moves in space 19 relative to coil 17 to produce electrical energy (see Figure 3 and col. 2, ln. 64-68 and col. 3, ln. 1-3).

Claim Rejections - 35 USC § 103

46. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

47. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hara. Hara discloses the invention essentially as claimed but fails to disclose the use of staples, sutures, or ties to attach the device the heart of a patient. The Examiner takes Official Notice that it is well known in the heart to use staples, sutures, or ties to attach devices to the heart of the patient in order to ensure that the device does not move relative to the heart and remains securely in place for the life of the device. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize staples, sutures, or ties to attach the device of Hara to the heart in

order to ensure that the device does not move relative to the heart and remains securely in place for the life of the device.

48. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lehr. Lehr discloses the invention essentially as claimed but fails to disclose the use of staples, sutures, or ties to attach the device the heart of a patient. The Examiner takes Official Notice that it is well known in the heart to use staples, sutures, or ties to attach devices to the heart of the patient in order to ensure that the device does not move relative to the heart and remains securely in place for the life of the device. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize staples, sutures, or ties to attach the device of Lehr to the heart in order to ensure that the device does not move relative to the heart and remains securely in place for the life of the device.

49. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hara. Hara discloses the invention essentially as claimed by fails to disclose that the first end of the device includes the ferromagnetic element. It would have been obvious to one having ordinary skill in the art at the time of the invention to locate the ferromagnetic element 24 at the first end of the device, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-

1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tammie K. Heller
Patent Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

TKH